

Conference Notice

PDE-5 Inhibition and HIV Risk: Current Concepts and Controversies

FDA, in collaboration with The University of Medicine and Dentistry of New Jersey, The National Institute of Mental Health, The National Institute on Drug Abuse, and The Centers for Disease Control and Prevention is announcing a consensus conference, *PDE-5 Inhibition and HIV Risk: Current Concepts and Controversies*. The objective of the conference is to bring together and review data related to the use of Phosphodiesterase type-5 inhibitors (PDE-5's) for the treatment of male erectile dysfunction, such as sildenafil, tadalafil, and vardenafil, and their relationship to HIV transmission in high risk men and their sexual partners.

The conference will address:

- PDE-5 use and sexual behavior among at-risk populations
- PDE-5 use in combination with drugs of abuse
- Risks and benefits of PDE-5 treatment in at-risk populations

Evidence-based guidelines will be developed for prevention, education and research on causes and consequences of high-risk sexual behavior.

The conference will take place September 26 and 27, 2005, at the [Bolger Conference Center](#) in Potomac, MD. Registration is required, and there is a registration fee for this conference (see link below).

PDE-5 INHIBITION IN HIV+ AND HIV- MEN: BIOMEDICAL, BEHAVIORAL AND SOCIETAL PERSPECTIVES

Phosphodiesterase type-5 inhibitors (PDE-5's) are highly effective and well-tolerated oral drugs for treatment of male erectile dysfunction (ED), a medical condition which affects about 180 million men, worldwide. Three specific drugs in this class (sildenafil, tadalafil, vardenafil) have been approved and are currently used by approximately 20-25 million men. Recent reports of potential use of these agents as "recreational drugs" by selected groups of men has raised concerns about a variety of health risks: primarily, the association of these drugs with high risk sexual risk behavior, as well as the increasing co-use with known drugs of abuse (e.g. crystal methamphetamines).

This conference will aim to bring together existing data on use of PDE5 inhibitors (with or without drugs of abuse) in men and women at risk sexually, or being treated for HIV, the potential impact on physical and mental health in users, and the possible threat of increased risk for HIV spread. A major goal of the proposed conference is to critically evaluate the available evidence of increased use of these drugs by high risk individuals, and their potential contribution to further high-risk sexual behavior in HIV+ or HIV- men. What are the epidemiological implications, if any, of these trends, and what steps should be taken in regard to prevention or education?

A related goal is to critically evaluate the state of knowledge regarding biobehavioral effects of PDE-5 inhibition on sexual behavior generally, and the potential pharmacological interactions with other prescription or non-prescription drugs. Both pharmacological and behavioral aspects of this association will be addressed.

A third major area of focus for the proposed conference will be on the treatment of sexual dysfunction in men with HIV/AIDS, and the potential risks and benefits of PDE-5 use in this group. Clinical management guidelines will be developed in this regard.

Finally, the conference will address legal, ethical and social policy aspects of PDE-5 use in high risk or HIV+ individuals. Potential initiatives for education and prevention, particularly those which involve collaboration of industry, academia and government will be explored.

Additional details and registration information can be found at <http://ccoe.umdj.edu/rwjms/PDE5/index.htm>.

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An archive of past list serve announcements is available on the FDA web site at <http://www.fda.gov/oashi/aids/listserve/archive.html>